



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement of Organization, Functions and Delegations of Authority

AGENCY: Administration for Strategic Preparedness and Response, HHS.

ACTION: Notice.

SUMMARY: This notice announces the establishment of the Administration for Strategic Preparedness and Response.

DATES: This reorganization was approved by the Secretary of Health and Human Services on January 27, 2023, and became effective on February 11, 2023.

SUPPLEMENTARY INFORMATION: Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority of the U.S. Department of Health and Human Services (HHS) is being amended at Chapter AN, Office of the Assistant Secretary for Preparedness and Response (ASPR), as last amended at 79 FR 70.535 (Nov. 26, 2014), 78 FR 25277 (April 30, 2013), 78 FR 7784 (Feb. 4, 2013), 75 FR 35.035 (June 21, 2010) to realign the functions of ASPR to reflect the changes mandated by the 21st Century Cures Act and the Pandemic and All-Hazards Preparedness and Advancing Innovation Act to address ever-increasing manmade and naturally occurring threats which degrade public health, access to healthcare, access to emergency medical services and national security. The changes are as follows.

- I. Under AN.10 Organization, delete all the components and replace with the following:
 - A. Immediate Office of the Administration for Strategic Preparedness and Response (SN)
 - B. Office of the Principal Deputy Assistant Secretary for Strategic Preparedness and Response (SN)
 - C. Office of Administration (SNA)
 - D. Office of Biomedical Advanced Research and Development Authority (SNB)

E. Office of HHS Coordination Operations and Response Element (H-CORE) (SNH)

F. Office of Industrial Base Management and Supply Chain (SNI)

G. Office of Preparedness (SNP)

H. Office of Response (SNR)

I. Office of Strategic National Stockpile (SNS)

II. Delete AN.20 Functions, in its entirety and replace with the following:

Section AR.20 Functions.

A. Immediate Office of the Administration for Strategic Preparedness and Response:

The Immediate Office of the Administration for Strategic Preparedness and Response (IO/ASPR) is headed by the Assistant Secretary, who provides leadership and executive and strategic direction for the ASPR organization. The Assistant Secretary is the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies. The Assistant Secretary is responsible for carrying out ASPR's mission and implementing the functions of ASPR. The IO/ASPR (1) ensures development and maintenance of liaison relationships with HHS operating and staff divisions and represents HHS at interagency meetings, as required; (2) oversees advanced research, development and procurement of qualified countermeasures, security countermeasures and qualified pandemic or epidemic products; (3) coordinates with relevant federal officials to ensure integration of public health policy and federal preparedness and response activities for public health emergencies; (4) coordinates the strategic and operational activities for public health preparedness response and recovery; and (5) establishes and maintains effective communications and outreach guidance and support for all external communications, including legislative and executive branch questions and inquiries, and serves as the principal advisor to the ASPR on all legislative strategies

to fulfill the Office of the ASPR and the HHS mission under section 2811 and other relevant sections of the Public Health Service Act, as amended.

The Immediate Office of the Administration for Strategic Preparedness and Response is headed by the Assistant Secretary (SN), and includes the following components:

- Office of External Affairs (SN1)
- Office of Legislative Affairs (SN2)
- Office of Public Affairs (SN3)

B. Office of the Deputy Assistant Secretary for Strategic Preparedness and Response (SN):

The Office of the Principal Deputy Assistant Secretary (OPDAS) is responsible for providing a well-integrated infrastructure that supports the Department's capabilities to prevent, prepare for, respond to, and recover from public health and medical threats and emergencies. The PDAS also serves as the Chief Operating Officer for ASPR.

The PDAS provides guidance and support to all elements within the ASPR on behalf of the Assistant Secretary. The PDAS is responsible for the execution of business management operations, including the management of correspondence control for the Assistant Secretary. The PDAS also manages coordination among HHS entities and external federal agencies in support of ASPR missions.

The Office of the Principal Deputy Assistant Secretary is headed by the Principal Deputy Assistant Secretary (SN), and includes the following components:

- Office of Strategy, Policy, and Requirements (SN4)
- Executive Secretariat (SN5)

C. Office of Administration (SNA):

The Office of Administration provides the administrative support services necessary to maintain day-to-day operations of ASPR, including functions of human resources, United States Public Health Service (USPHS) liaison, acquisitions management to

include policy and operational contracting, grants management, information technology, facilities and all financial planning and analysis. The Office of Administration is headed by a Deputy Assistant Secretary and includes the following components:

- Office of Head of Contracting Activity (HCA) (SNA1)
- Office of Finance (SNA2)
- Office of Human Capital (SNA3)
- Office of Information Technology (SNA4)

D. Office of Biomedical Advanced Research and Development Authority (SNB):

The Office of Biomedical Advanced Research and Development Authority (BARDA), established in April 2007 in response to the Pandemic and All-Hazards Preparedness Act of 2006, serves preparedness and response roles to provide medical countermeasures (MCM) in order to mitigate the medical consequences of chemical, biological, radiological, and nuclear (CBRN) threats and agents and emerging infectious diseases, including pandemic influenza. BARDA executes this mission by facilitating research, development, innovation, and acquisition of MCM and expanding domestic manufacturing infrastructure and surge capacity of these MCM. BARDA is headed by a Director, who is also referred to as a Deputy Assistant Secretary, and includes the following components:

- Office of Medical Countermeasures Program Support Services (SNB2)
- Office of Medical Countermeasures Program (SNB3)

E. Office of HHS Coordination, Operations and Response Element (SNH):

In 2022, the Secretary of HHS transitioned the DOD-HHS partnership that was formerly called Operation Warp Speed into ASPR as the HHS Coordination and Operations Response Element or H-CORE. Moving H-CORE fully into ASPR gives

ASPR sole responsibility for the development, manufacture, and distribution of the nation's COVID-19 vaccines and therapeutics.

H-CORE works in partnership with other entities across ASPR, such as, the Biomedical Advanced Research and Development Authority (BARDA), the Strategic National Stockpile (SNS) and other HHS and Interagency partners, to deliver COVID-19 countermeasures to the American public while solidifying enhanced capability to respond to future public-health threats.

The Office of HHS Coordination, Operations and Response Element is headed by a Deputy Assistant Secretary and includes the following components:

- Office of Plans (SNH1)
- Office of Analytics (SNH2)
- Office of Security and Assurance (SNH3)
- Office of Supply, Production, and Distribution (SNH4)
- Office of Vaccine Development Coordination (SNH5)
- Office of Therapeutics Development Coordination (SNH6)

F. Office of Industrial Base Management and Supply Chain (SNI):

The Office of Industrial Base Management and Supply Chain seeks to build permanent Industrial Base Expansion (IBx) capabilities, inclusive of global supply chain situational awareness, market capabilities, and rapid acquisition execution, to reinforce ASPR as the authority to coordinate the activities related to medical industrial base expansion and sustainment through the use of Defense Production Act and Emergency Support Function (ESF) 8 authorities. Efforts under Presidential Executive Orders have already galvanized a large part of the interagency to fully implement HHS and national strategies. HHS is expanding the Public Health Industrial Base and developing innovative solutions to address critical deficiencies in

the public health supply chain by working across the U.S. Government and with academia and the private sector.

The Office of Industrial Base Management and Supply Chain is headed by a Deputy Assistant Secretary and includes the following components:

- Office of Personal Protective Equipment and Durable Medical Equipment (SNI1)
- Office Testing and Diagnostics (SNI2)
- Office of Advanced Manufacturing Technologies (SNI3)
- Office of Supply Chain Optimization (SNI4)
- Office of Defense Production Act and Emergency Response Authorities (SNI5)

G. Office of Preparedness (SNP):

The Office of Preparedness is responsible for policy development, planning, analysis, requirements, and strategic planning. This Office also manages and operates the HHS Secretary's Operation Center (SOC), intelligence, security, information management and analysis, and is also responsible for the HHS Continuity of Operations (COOP) and the development of the ASPR COOP Plan.

The Office of Preparedness is headed by a Deputy Assistant Secretary and includes the following components:

- Office of Security and Intelligence (SNP1)
- Office of Information Management Data and Analytics (SNP2)
- Office of Critical Infrastructure Protection (SNP3)
- Office of Health Care Readiness (SNP4)
- Office of Medical Reserve Corps (SNP5)
- Office of Planning and Exercises (SNP6)
- Office of Continuity (SNP7)

- Office of Secretary's Operations Center (SNP8)

H. Office of Response (SNR):

The Office of Response oversees activities required to coordinate public health and healthcare response systems and activities with relevant federal, state, tribal, territorial, local, and international communities under the National Response Framework and Emergency Support Annexes #8, #6 and #14. This Office also provides oversight and guidance to the National Disaster Medical System and provides an important liaison function to other agencies engaged in federal response activities.

The Office of Response is headed by a Deputy Assistant Secretary and includes the following components:

- Office of Regional Response (SNR1)
- Office of Response Logistics (SNR2)
- Office of National Disaster Medical System (SNR3)
- Office of Community Mitigation and Recovery (SNR4)

I. Office of the Strategic National Stockpile (SNS):

The Strategic National Stockpile (SNS) is part of the federal medical response infrastructure and can supplement medical countermeasures needed by states, tribal nations, territories, and the largest metropolitan areas during public health emergencies. The supplies, medicines, and devices for lifesaving care contained in the stockpile can be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient. The SNS team works every day to prepare and respond to emergencies, support state and local preparedness activities, and ensure availability of critical medical assets to protect the health of Americans.

The Office of the Strategic National Stockpile is headed by a Deputy Assistant Secretary and includes the following components:

- Office of Management and Business Operations (SNS1)
- Office of Logistics (SNS2)
- Office of State Tribal Local and Territories Preparedness (SNS3)
- Office of National Readiness and Response (SNS4)
- Office of Supply Chain Alliance and Development (SNS5)
- Office of Science (SNS6)

III. Delegations of Authority.

All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

Xavier Becerra,
Secretary,
Department of Health and Human Services.

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